

**REMARKS**

The pending Office Action addresses and rejects claims 1-6, 11-13, 15, 24, and 37-40. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

***Amendments to the Specification***

Applicants amend the specification to correct two typographical errors. No new matter is added.

***Amendments to the Claims***

Applicants amend claims 1 and 24 to recite that the distal portion of the body is configured to selectively engage the support. Support for these amendments can be found throughout the specification and drawings. No new matter is added.

***Claim Rejections Pursuant to 35 U.S.C. § 102***

The Examiner rejects claims 1-6, 15, and 37 pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,375,655 of Zdeblick et al. ("Zdeblick"), arguing that Zdeblick discloses the claimed invention. Applicants respectfully disagree.

Amended independent claim 1 recites an intervertebral fusion device. The device includes a body that has a proximal portion and a distal portion along a major axis. The body defines a conduit substantially parallel to the major axis and the conduit extends throughout the body. The device also includes a support at the distal portion that is configured to support vertebrae in a distracted position while the vertebrae fuse. The support includes a conduit in fluid communication with the conduit defined by the body and that has at least one outlet on a surface of the support. The claim also requires that the *distal portion of the body be configured to selectively engage the support* and at least a portion of the body or the support has a height distinct from a width taken along a cross-section of the portion of the body or support perpendicular to the major axis. The portion of the body or support can distract vertebrae between which the portion is placed by rotation of the body or support about the major axis.

Zdeblick fails to teach or even suggest the device of claim 1 because it lacks a body with a

distal portion that is configured to selectively engage a support. As shown in Figures 9-10 of Zdeblick, the structure relied upon by the Examiner as being a “body,” the sleeve (52), is not in any way configured to selectively engage a support. In fact, the sleeve (52) does not even touch the support (10), much less selectively engage it. Instead, as discussed in the Zdeblick specification at column 9, lines 45-50, the support (10) is only engaged by tongs (54) formed at one end of a shaft (51).

Applicants note that the Examiner incorrectly states on page 2 of the office action that the “body” has a proximal end (54). The Examiner regards sleeve (52) as the body, as noted above and in the office action. The element designated as proximal portion (54) is not part of the sleeve or body (54) – it is part of shaft (51).

For the reasons noted above, Zdeblick does not disclose a “body” having a distal portion that in any way, let alone selectively, engages the support. As explained above, tongs (54) of Zdeblick are not part of what the Examiner regards as the “body” (52). Tongs (54) are part of the shaft (51). The shaft (51), as explained in previous responses, lacks any conduit extending therethrough and in communication with a conduit extending through the support.

These differences are alone sufficient to require withdrawal of the pending rejection.

Additionally, Zdeblick lacks a conduit that extends throughout a body, as further required by claim 1. A conduit is defined as “a natural or artificial channel through which water or other fluid passes or is conveyed.” *Webster’s Third New International Dictionary* (1993). As shown in Figure 9 of Zdeblick, fluid cannot be passed or conveyed through any part of the sleeve (52) when it is assembled with the shaft (51) to form an implant driver (50). Instead, the shaft (51) and the threaded interface (65) completely fill the inner lumen of the sleeve (52) and block its proximal opening. Therefore the sleeve (52) cannot be considered a body with a conduit that extends throughout, as expressly required by claim 1.

Accordingly, independent claim 1 distinguishes over Zdeblick and represents allowable subject matter. Claims 2-6, 15, and 37 are allowable at least because they depend from an allowable base claim.

***Claim Rejections Pursuant to 35 U.S.C. § 103 – “Zdeblick / Mathews”***

The Examiner rejects claims 11-13, 24, and 39-40 pursuant to 35 U.S.C. § 103(a) as being obvious over Zdeblick in view of U.S. Publication No. 2003/0028251 of Mathews ("Mathews"). Applicants respectfully disagree.

Claims 11-13 and 24

Amended claims 1 and 24 both recite an intervertebral fusion device that includes a body with a distal portion configured to selectively engage a support. As discussed above, Zdeblick fails to teach or even suggest this limitation. Mathews fails to remedy this deficiency in Zdeblick because nowhere in the Mathews specification or drawings is a body with a distal portion configured to selectively engage a support discussed, contemplated, suggested, or implied. In fact, as shown in Figures 2A-3C and Figures 8-17C of Mathews, the balloon support is rigidly and permanently attached to a shaft, not selectively engaged to it as required by claims 1 and 24.

Accordingly, the combination of Zdeblick and Mathews fails to render claim 1 or claim 24 obvious and therefore both claims represent allowable subject matter. Claims 11-13 are allowable at least because they depend from an allowable base claim.

Claims 39-40

Independent claim 39 recites an intervertebral fusion device that includes a body that has proximal and distal portions along a major axis. The body defines a conduit substantially parallel to the major axis and the conduit extends throughout the body. The intervertebral fusion device also includes a selectively expandable balloon at the distal portion that is configured to support vertebrae in a distracted position while the vertebrae fuse. An inner volume of the expandable balloon is in fluid communication with the conduit defined in the body and the balloon is formed of a biodegradable polymer.

The Examiner concedes that Zdeblick lacks a balloon formed of a biodegradable polymer and relies on paragraph 0053 of the Mathews specification to remedy this deficiency. *Office Action* at 3. This paragraph however describes the fill material of the Mathews invention, not the balloon itself. The concept of forming the balloon of a biodegradable polymer is not taught or suggested anywhere in Mathews. Moreover, no person skilled in the art would be motivated to make the Mathews balloon biodegradable, since it is designed to be removed from the patient before the surgery even

ends.

Accordingly, Mathews fails to resolve the deficiency in Zdeblick with respect to the biodegradable balloon of claim 39 and therefore claim 39 is not rendered obvious by the combination of Zdeblick and Mathews. Claim 39, and claim 40 which depends therefrom, thus represent allowable subject matter.

***Claim Rejections Pursuant to 35 U.S.C. § 103 – “Zdeblick / Nicholson”***

The Examiner rejects claim 38 pursuant to 35 U.S.C. § 103(a) as being obvious over Zdeblick in view of U.S. Patent No. 6,258,094 of Nicholson et al. (“Nicholson”). Applicants respectfully disagree.

Claim 38 recites the intervertebral fusion device of claim 1, wherein the support is biodegradable. As discussed above, independent claim 1 represents allowable subject matter and accordingly, claim 38, which depends directly therefrom, is also allowable.

Moreover, Nicholson fails to remedy the deficiencies of Zdeblick with respect to claim 38. The Examiner concedes that Zdeblick fails to teach a biodegradable support. *See Office Action* at 4. Nicholson fails to remedy this deficiency because it too lacks a biodegradable support. Instead, as discussed in the Nicholson specification at column 12, lines 25-40, the support in Nicholson is merely capable of being *encased* in a thin biodegradable shell. The support itself is not biodegradable, as expressly required by claim 38. Accordingly, the combination of Zdeblick and Nicholson fails to teach or even suggest the claimed invention and therefore claim 38 represents allowable subject matter.

***Conclusion***

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants’ amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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